Proposed Page content:

Maine CDC Office of the Director

Human Research and Data Privacy Protections

Background and Purpose

The Maine Center for Disease Control and Prevention (Maine CDC) collects and uses a wide variety of health data for the purposes of protecting and promoting health and preventing disease. Due to the sensitive nature of much of the data Maine CDC collects, special policies and procedures have been developed that reflect best practices in protecting privacy and assuring ethical practices by our staff. These policies are consistent with applicable state and federal law.

Data Collection, Storage, Sharing and Dissemination

The Privacy Policy of the Maine Center for Disease Control and Prevention (Revised and Adopted 5-1-2006) outlines Maine CDC policy concerning data privacy, confidentiality and security. The goal of the policy is to assure the broadest possible access to public health data while at the same time maintaining strict standards for data confidentiality and security. In addition, the policy requires uniform practices among all Maine CDC divisions and programs. When appropriate, the minimum standards outlined in this policy may be augmented to better meet individual program needs or requirements.

The Maine CDC is committed to safeguard, protect and secure all individually identifiable health information entrusted to it in accordance with applicable state or federal law. Although this Privacy Policy establishes general policy practices which shall govern operations, this document shall not be considered an exhaustive document regarding health care information privacy and security. Units of the Maine CDC subject to more restrictive criteria regarding the use, administration, management, processing, storage, disclosure and sharing of individual identifiable health information gathered, furnished or developed by the Maine CDC shall abide by such restrictions.

To the extent a unit of the Maine CDC is considered a covered entity within the meaning of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (P.L. 104-91, codified at 42 U.S.C. §§ 1320 (d)(1)-(d)(8)), the applicable standards, rules and regulations established under that statute are applicable to the particular unit of the Maine CDC. (See the complete Privacy Policy (link here)

All staff members of the Maine CDC are responsible for understanding and using the Privacy Policy as it applies to the performance of the job functions. Maine CDC Program Managers and Division Directors have particular responsibilities

for assuring the Privacy Policy is implemented, particularly its requirements regarding data inventory, sharing and release.

Annual, required training for all Maine CDC staff on the Privacy Policy will begin in the summer of 2006.

Research

All research involving human participants conducted by the Maine CDC or funded in whole or in part by Maine CDC must comply with the Code of Federal Regulations, Title 45, Part 46-Protection of Human Subjects (45 CFR 46). This includes research conducted by Maine CDC employees, either directly, through, cooperative agreements or contracts or in collaboration with outside parties.

All research must be approved by an Institutional Review Board (IRB) prior to the start of the research.

For additional information, please review the materials linked to this web page. If you have questions that are not answered after reviewing these materials, contact Bob Woods, Chairperson, Maine CDC Institutional Review Board at Bob.Woods@Maine.gov or 207-287-5199.

Research Review Process:

Maine CDC's Institutional Review Board (IRB) was established in 2000. It operates on the basis of guiding principles (link) and under the policies and procedures established by federal statute (Title 45CFR46 (link)) It has a Federal Wide Assurance, meaning its actions are recognized by all federal funding agencies (link to OHPR.) Maine CDC's IRB members are appointed by the Director and serve for 3 year terms. Members come from both inside and outside Maine CDC and represent multiple professional disciplines as well as the public (link.)

The review process (link to flow chart) begins with an initial determination by the IRB Chairperson (or their designee) as to whether or not a project is research or public health practice (link to research vs practice table.) ***Because all staff and their program managers have an inherent conflict of interest in this step, a staff member, supervisor or division director cannot make this determination her or himself. A formal request must be made in writing to the IRB Chair*** (email is acceptable: Bob.Woods@Maine.gov) The formal written request must provide adequate information for the Chair to make the initial determination and must include:

Project Title
Affiliated Maine CDC Program
Maine CDC Staff Involved (Principal and Co-investigators)
Outside Partner Agencies and Staff Involved
Description of Purpose
Description of Methods

If the Chair determines the project is not research, the Chair will provide written documentation to that effect to the lead staff person for the Program's records.

If the Chair determines the project is research, the Chair will advise the Principal Investigator in writing and advise whether the project might be exempt research, eligible for expedited review or full-IRB review.

All research projects must have a protocol that completely addresses all relevant points in the attached protocol checklist (link)

New protocols must be accompanied by a completed and *signed* protocol form: either a new protocol application (link), an exempt protocol application (link) or an application for expedited review (link) depending on the advice of the IRB Chair.

In addition, consent, assent and/or enrollment forms must address all relevant points in the attached consent form checklist (link) and meet readability standards (link)

If the research involves pregnant women, children or prisoners, additional requirements must be met by the protocol and the consent forms (link to CDC site)
Two (2) copies of all complete, *signed* applications should be hand-delivered to Robert Burman, Special Assistant for Operations, Office of the Director-Maine CDC, 8th Floor, Key Plaza, 286 Water St., Augusta, Maine 04330. (Phone: 207-287-8164) The application will be entered into the IRB protocol tracking database, a hardcopy file created, and the application will be delivered to the IRB Chair for further action (link to protocol process) Principal Investigators can contact Mr. Burman or the IRB Chair for updates on application review process.

All IRB actions will be documented by the IRB Chair and communicated in both email and hard copy formats to the Principal Investigator.

Subsequent to approval of a protocol, the Principal Investigator is responsible for notifying the IRB of adverse events (link) or requesting amendments to the protocol (link). Additionally, all Principal Investigators must submit annual requests for continuation of protocols (link) or termination of protocols (link)

If you have questions that are not answered after reviewing these materials, contact Bob Woods, Chairperson, Maine CDC Institutional Review Board at Bob.Woods@Maine.gov or 207-287-5199.

(All the links referenced above are files attached to the email or can be found below)
Additional Info Links to the page:

General information and website of the federal DHHS Office for Human Research Protections:
http://www.hhs.gov/ohrp/

Federal Regulations under which IRB's operate (Title 45 CFR, revised June 23, 2005):

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Federal Centers for Disease Control and Prevention's Office of the Chief Science Officer (Includes links to CDC's Office of Public Health Research and its Institutional Review Board policies, procedures and background papers):
http://www.cdc.gov/od/ads/index.htm

Federal CDC's Human Subject's Documents (including forms and checklists)
http://www.cdc.gov/od/ads/hsrdocs.htm

Important background documents related to ethical research and protection of human subjects:
The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
http://www.cdc.gov/od/ads/ethcodes/belm-eng.pdf

World Medical Association Declaration Of Helsinki: Ethical Principles for Medical Research Involving Human Subjects
http://www.wma.net/e/policy/b3.htm